REMARKS

The last Office Action has been carefully considered.

It is noted that claims 1, 2, 3, 4, 5, 6, 7, 8, and 9 are rejected under 35 U.S.C. 102(e) over the patent to Matson.

Claims 1-11 are rejected under 35 U.S.C. 103(a) over the patent to Matson in view of the patent to Davankov.

Also, the claims are rejected under 35 U.S.C. 112.

Before analysis of the Examiner's rejection over the prior art, it is believed to be advisable to analyze the Examiner's rejection for formal reasons under 35 U.S.C. 112.

The Examiner indicated that the teachings of the specification are limited to specific co-polymeric beads and do not provide written description of a representative number of beads and fibers.

As for the actual number of the particles in the system in accordance

with the present invention, it is believed that such information can not be considered as necessary, since how many particles are contained in the particulate hemocompatible polymer material for removing toxins depends on practical requirements for passing blood through the polymer material, in particular the quantity of blood, the speed of passage of the blood, etc. the selection of the volume of the polymer material and therefore the number of the particles is conventional for a person of ordinary skill in the art, and does not need additional details.

If the Examiner is questioning the number of types of the beads or the materials which are used for producing the beads, claims 9, 10 and 11 disclose these features. In particular, claim 9 defines that the particles of the groups are composed of crosslinked polymeric material prepared by polymerization of monomers selected from the groups consisting of sterene ethylstyrene, α-methylstyrene, divinylbenzene, diisopropenylbenzene, trivinylbenzene, alkyl methacrylate as methyl methacrylate, and buthyl methacrylate. Claim 10 defined that the particles of the first group have positively charged function groups, covalently bonded to a surface of pores of said particles of said first group and selected from the group consisting amino-, methylamino-, ethylamino-, dimethylamino-, diethylamino-, ethanolamino-, diethanolamino-, polyethylenimino-groups, imidazole, and

histamine. Claim 11 defines that the particles of the groups have hydrophilic, compatible coating, composed of a material selected from the group consisting of polyvinylpyrrolidone, polyhydroxyethyl methacrylate, carboxymethylcellulose, and polyurethane.

The Examiner's attention is respectfully directed to first paragraph on page 12 of the specification. The specification does disclose the above mentioned materials which are defined in claims 9, 10, and 11. Thus, it is believed that the specification does have a support for the number of materials for the beads as defined in the claims.

The Examiner further questions the relative functions and/or structure of hydrophobic/hydrophilic, mesoporous/microporous materials, as well as binding of endotoxins or superantigens and cytokines. It is respectfully submitted that in the adsorption technique, both in science of adsorption and in industry which uses adsorption the above mentioned terms are generally known and well established. By definition a hydrophobic material is a material which repels aqueous media, while a hydrophilic material is a material which attracts aqueous media, and there can be no double-guessing about the differences between these materials and it is believed that no additional explanation is needed. Since the materials of the

present invention are polymers, it is well established in the polymeric technology that polar polymers are hydrophilic and non-polar polymers are hydrophobic. Thus, it is believed that these terms are clear and no additional definition is needed.

The same is true with respect to the mesoporous and microporous particles. The meaning of these terms is well established. In addition, on page 10, in paragraph 2 where the macroporous polymeric particles are described, the size of the pores of these particlesis presented, and in paragraph 2 on page 11 where the mesoporous polymeric particles are described the size of the pores of these particles is also specifically presented. Thus, these terms are also known, and in addition described in the specification.

The nature of binding of endotoxin as well as superantigens and cytokines is also specifically described in the specification. Paragraphs 2 and 3 on page 10 explain how endotoxins are bound to the polymer particles, and in second paragraph on page 11 it is described how cytokines and superantigens are bound to the surface of the particles. Finally, as for the specific examples given for the system in accordance with the present invention, the specification provides an example for the system, and it is

believed that it is not mandatory to provide more examples, since there is no specific requirement how many examples are needed in order to support a specific invention. The Examiner is respectfully requested to clarify this issue, and applicants would be pleased to provide additional examples if necessary.

The Examiner indicated that Example 1 is not completely clear. In connection with this, applicants have amended the corresponding part of the specification. In particular, the Example 2 specifically describes how to produce a material with a porous hydrophobic core having a few positively charged groups, and in Example 2 is specifically stated that all other steps are similar to the Example 1. Therefore, the example has been clarified to specifically show this particular feature. As for the production of the polymeric particles of the second group, the example clearly teaches the process. It is believed therefore that the specification is complete in disclosing the process of producing of the polymeric particles of the first group and the process of producing the polymeric particles of the second group. As for the fracture how to produce polymeric particles with different pore sizes, the technique is well known in the art, and it is believed that it is not necessary to explain it in detail.

In the Examiner's opinion the specification fails to teach that the particles are effective to treat infection or sepsis in the manner contemplated by the specification. The Examiner's attention is respectfully directed to the background of the invention section of the specification where it is specifically explained what is the relationship between endotoxins as well as superantigens and cytokines and infection or sepsis. This relation has been established by numerous scientific researches and has been generally proven. As disclosed in the last paragraph on page 7 of the specification, when blood from a patient is passed through the system in accordance with the present invention, entoxins, cytokines, and superantigens are removed from blood and blood is purified from the above mentioned toxins, so that septic shock is reliably prevented. It is believed to be clear that since infectious and septic shock is caused by the above mentioned toxins, and the system in accordance with the present invention removes these toxins, the septic shock is prevented.

It is respectfully submitted that the above presented information clearly answers the questions raised by the Examiner, it proves that the specification is complete in disclosing the present invention, and therefore the Examiner's formal rejections under 35 U.S.C. 112 should be considered as no longer tenable and should be withdrawn.

Turning now to the Examiner's rejection of the claims over the art, the Examiner rejected the claims over the patent to Matson as clearly anticipated, it is respectfully submitted that this reference deals with hemofiltration systems, methods and devices used to treat inflammatory mediator related diseases. As the Examiner correctly indicated, this reference discloses the information about the inflammatory mediators, such as cytokines and endotoxins. The reference also discloses a hemofiltration system with an absorbent device with one or more chambers containing absorbent material. The reference has been thoroughly studied. While the reference discloses a possibility of using various particles, it does not disclose a system in which a particulate hemocompatible material includes a first group of macroporous particles which are hydrophobic and positively charged to provide adherence of endotoxin to an inner surface of the particles and the second group of mesoporous particles which are hydrophobic and not charged and have a pore size selected so that cytokines and superantigens adhere to an inner surface of the particles of this group so as to simultaneously purify blood from endotoxins, cytokines and superantigens and thereby to treat serious infections and sepsis. The general statement about the possibility of using certain particles or even different particles does not provide any disclosure in this reference for a particulate hemocompatible material which would be similar or identical to

the material defined in claim 1, which is the core of the present invention.

Thus, it is believed that the patent to Matson taken singly does not disclose the new features of the present invention as defined in claim 1, these features can not be derived from this reference as a matter of obviousness, and therefore the Examiner's rejection of claim 1 over this reference should be considered as no longer tenable and should be withdrawn.

The patent to Davankov teaches sorbents for removing blood toxicants comprising a hypercrosslinked styrene resin with a surface modified to be biocompatible. While this is completely true, this reference however also does not teach the new features of the present invention. In particular, it does not teach such a particulate hemocompatible material which includes a first group of macroporous particles which are hydrophobic and positively charged to provide adherence of endotoxin to an inner surface of particles of the first group, and also a second group of mesoporous particles which are hydrophobic and are not charged and have a pore size selected so that cytokines and superantigens adhere to an inner surface of the particles of the second group so as to simultaneously purify blood from endotoxins, cytokines and superantigens and thereby to treat serious infections and

sepsis. Thus, this reference taken singly also does not teach the new features of the present invention which are now defined in claim 1.

The claims were also rejected by the Examiner over the combination of the teachings of these references under 35 U.S.C. 103. It is respectfully submitted that even if the teaching of the references were combined, a material produced from such a combination would not be the material of the applicant's invention, such a hypothetical system would not include the material as defined now in claim 1.

It is believed that in order to arrive at the applicant's invention from the references taken singly or from a combination of the references, the references have to be fundamentally modified by including into them the features which are specifically defined in claim 1 and not disclosed in the references. However, it is known that in order to arrive at a claimed invention, by modifying the references the cited art must itself contain a suggestion for such a modification.

This principle has also been consistently upheld by the U.S. Court of Customs and Patent Appeals which, for example, held in its decision in re Randol and Redford (165 USPQ 586) that

> Prior patents are references only for what they clearly disclose or suggestion; it is not a proper use of a patent as a reference to modify its structure to one which prior art references do not suggest.

Definitely, the references do not contain any hint or suggestion for such modifications.

As explained in detail in the application, the system in accordance with the present invention provides for the highly advantageous results in efficiently removing, simultaneously, endotoxins, as well as superantigens and cytokines from blood, and therefore to reliably prevent sceptic shock. It is well known that in order to support a valid rejection the art must also suggest that it would accomplish applicant's results. This was stated by the Patent Office Board of Appeals, in the case Ex parte Tanaka, Marushima and Takahashi (174 USPQ 38), as follows:

> Claims are not rejected on the ground that it would be obvious to one of ordinary skill in the art to rewire prior art devices in order to accomplish applicants' result, since there is no suggestion in prior art that such a result could be accomplished by so modifying prior art devices.

In view of the above presented remarks and amendments, it is believed that claim 1, the broadest claim on file, should be considered as patentably distinguishing over the art and should be allowed.

As for the dependent claims, these claims depend on claim 1, they share its presumably allowable features, and therefore it is submitted that they should be allowed as well.

Reconsideration and allowance of the present application is most respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects in order to place this case in condition for final allowance, then it is respectfully requested that such amendments or corrections be carried out by Examiner's Amendment, and the case be passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, he is invited to telephone the undersigned (at 631-243-3818).

Respectfully submitted,

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